



CDC/IDSA Clinician Call

June 6, 2023

Welcome & Introductions



Dana Wollins, DrPH, MGC
Senior Vice President, Strategy
Infectious Diseases Society of America

- 98th in a series of calls, initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

CDC/IDSA Clinician Call: Ending of the COVID-19 Public Health Emergency & Other Related Changes: What Clinicians Need to Know

1. Ending of the PHE: Overview & Implications for Surveillance, Infection Prevention & Control



Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
COVID-19 Response Clinical Team
Late Sequelae Unit
U.S. Centers for Disease Control and Prevention



Michael Stevens, MD, MPH, FSHEA, FIDSA, FACP
System Healthcare Epidemiologist
Associate CQO for Infection Prevention &
Antimicrobial Stewardship, WVU Health System
Professor of Internal Medicine & Public
Health, West Virginia University

2. Availability & Commercialization of Vaccines, Treatment



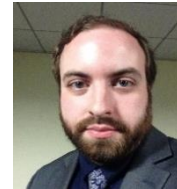
Meghan E. Pennini, PhD
Chief Vaccine and Therapeutic Officer
HHS Coordination Operations and Response Element
Administration for Strategic Preparedness & Response
U.S. Department of Health and Human Services

3. Moving from Emergency Use Authorization to Approval of COVID-19 Treatments: Paxlovid Update



John Farley, MD, MPH
Director, Office of Infectious Diseases
Office of New Drugs, Center for Drug Evaluation
and Research
U.S. Food and Drug Administration

4. Coverage, Costs & Payment Updates



Will Harris, JD
Senior Advisor, Office of the Administrator
Centers for Medicare & Medicaid Services

5. Q&A and Discussion

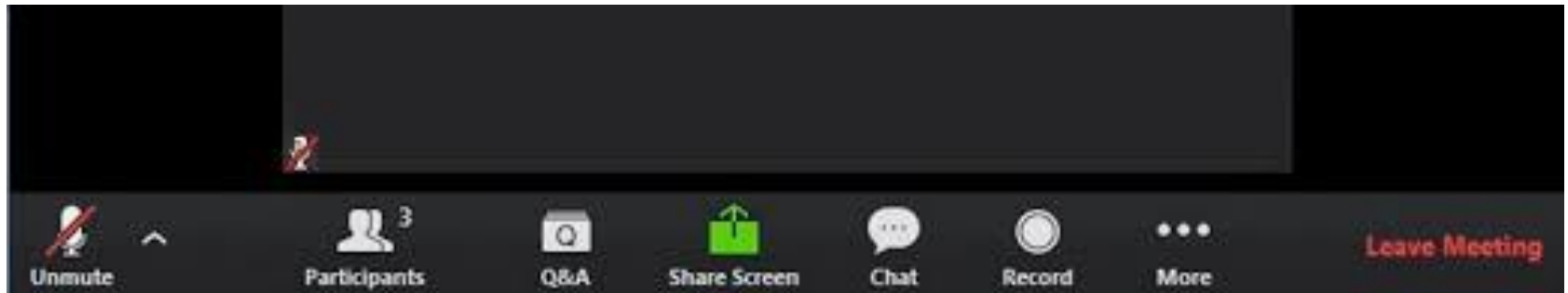


All panel members plus:
Alex J. Kallen, MD, MPH
Chief, Prevention and Response Branch
Division of Healthcare Quality Promotion
U.S. Centers for Disease Control and Prevention

Question?
Use the “Q&A” Button



Comment?
Use the “Chat” Button



Ending of the PHE: Overview & Implications for Surveillance, Infection Prevention & Control

**Brendan Jackson, MD, MPH
CDC**

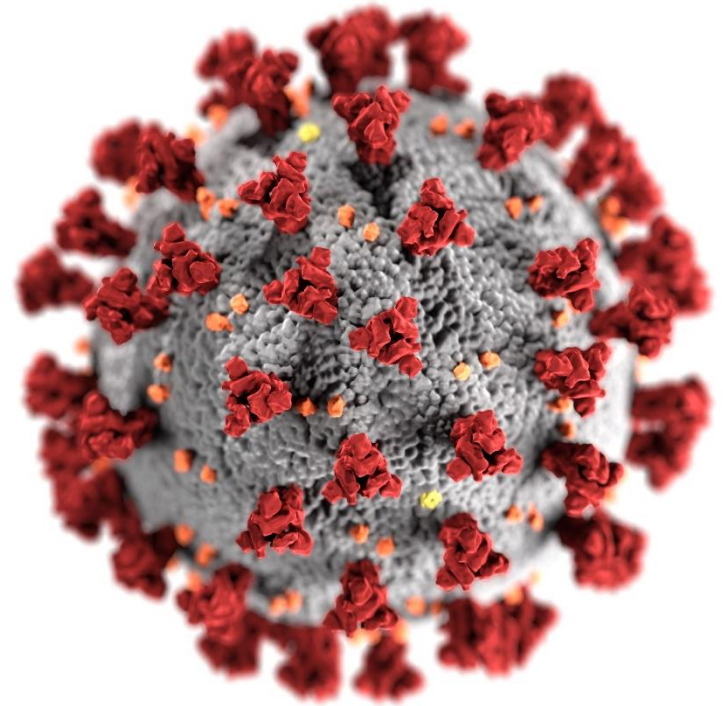
**Michael Stevens, MD, MPH, FSHEA, FIDSA, FACP
West Virginia University**

End of COVID-19 Public Health Emergency Declaration

**Implications for Public Health
Surveillance, Prevention, and Control**

IDSA Clinician Call

Brendan Jackson, MD, MPH
COVID-19 Incident Manager



cdc.gov/coronavirus

While the PHE ended, COVID-19 has not

End of the Federal COVID-19 Public Health Emergency (PHE) Declaration

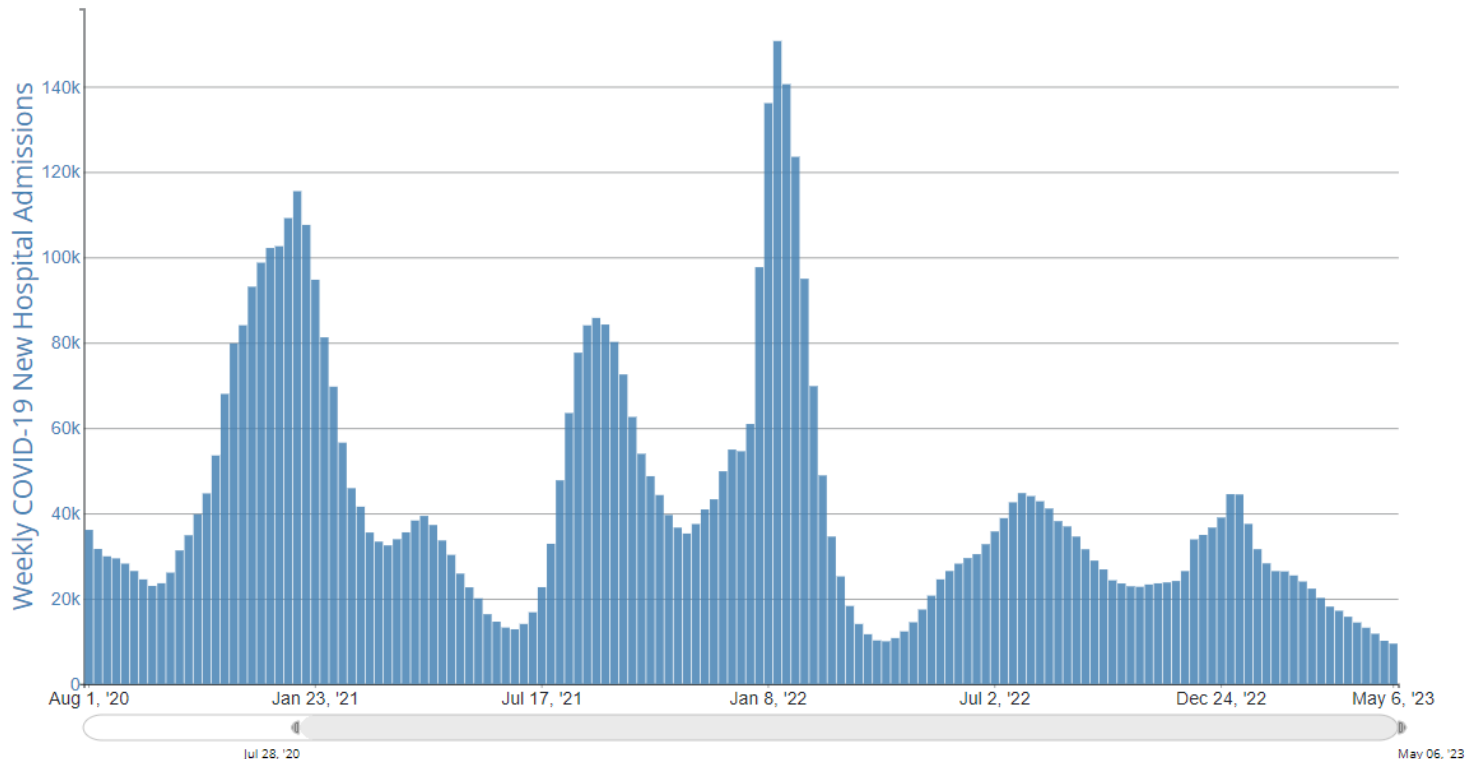
Updated May 5, 2023 [Español](#) | [Other Languages](#) [Print](#)

What You Need to Know

- The federal COVID-19 PHE declaration will end on May 11, 2023.
- Most tools, like vaccines, treatments, and testing, will remain available.
- CDC's ability to collect and share certain data will change.
- CDC is updating its guidance to align with data changes.

Hospitalizations as main way to track COVID-19 trends, new link to community guidance

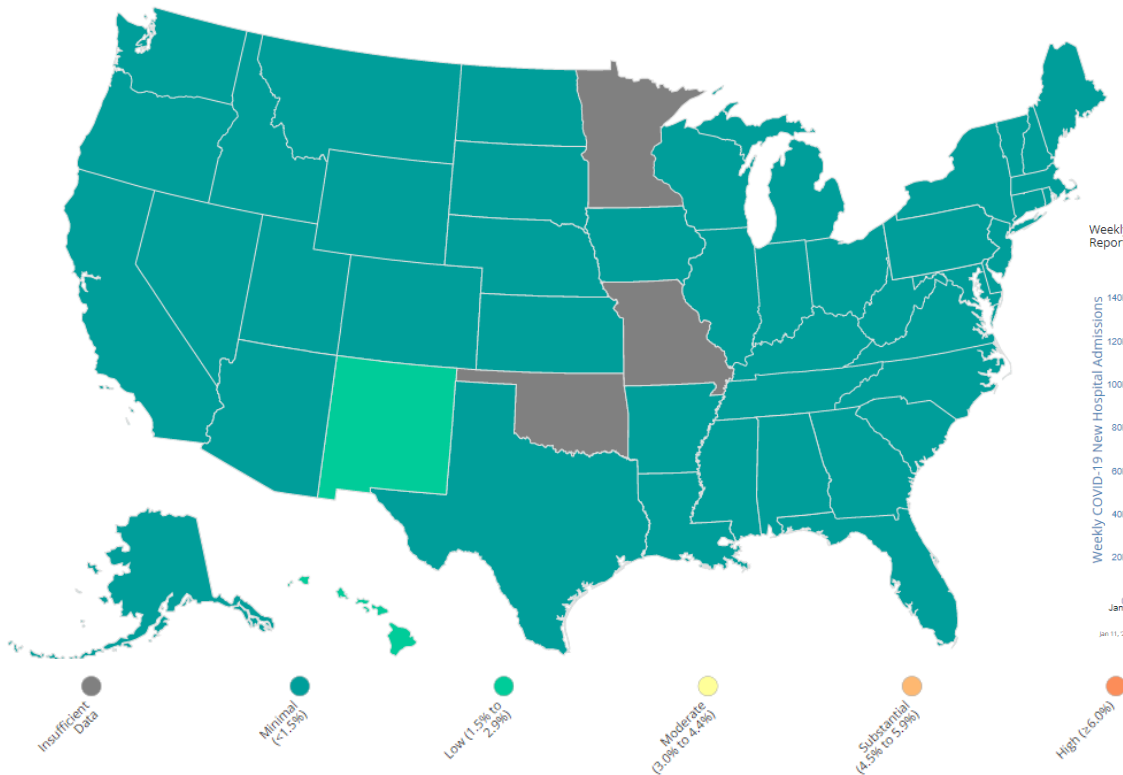
Weekly Trends in COVID-19 New Hospital Admissions in The United States Reported to CDC



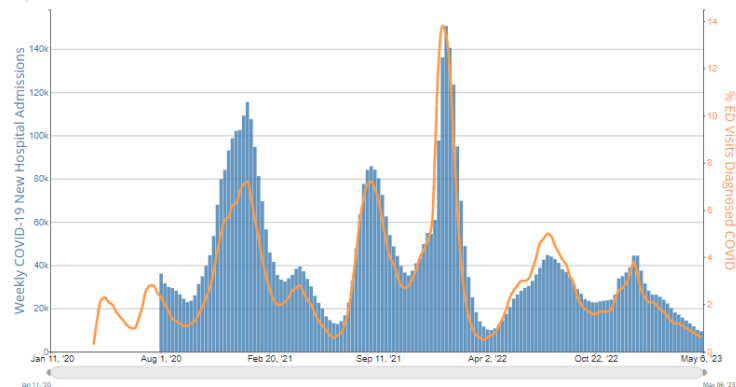
[CDC COVID Data Tracker: Trends by Geographic Area](#)

Emergency department visits are an excellent early indicator of spread

US Percent of NSSP Emergency Department (ED) Visits with Diagnosed COVID-19 in the Past Week, by State/Territory



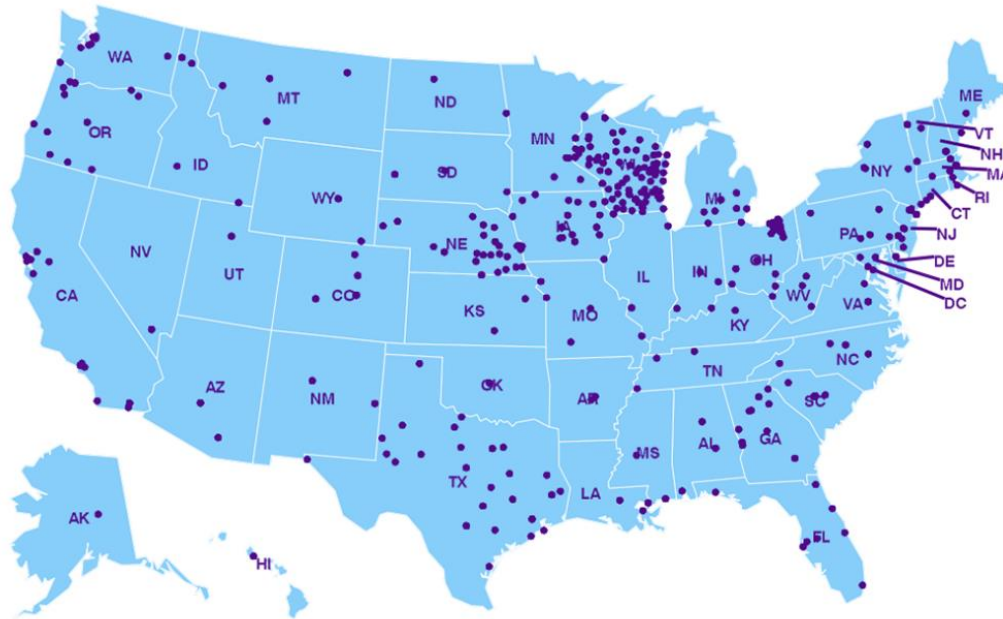
Weekly Trends in COVID-19 New Hospital Admissions and Percentage of ED visits with Diagnosed COVID-19 in The United States Reported to CDC



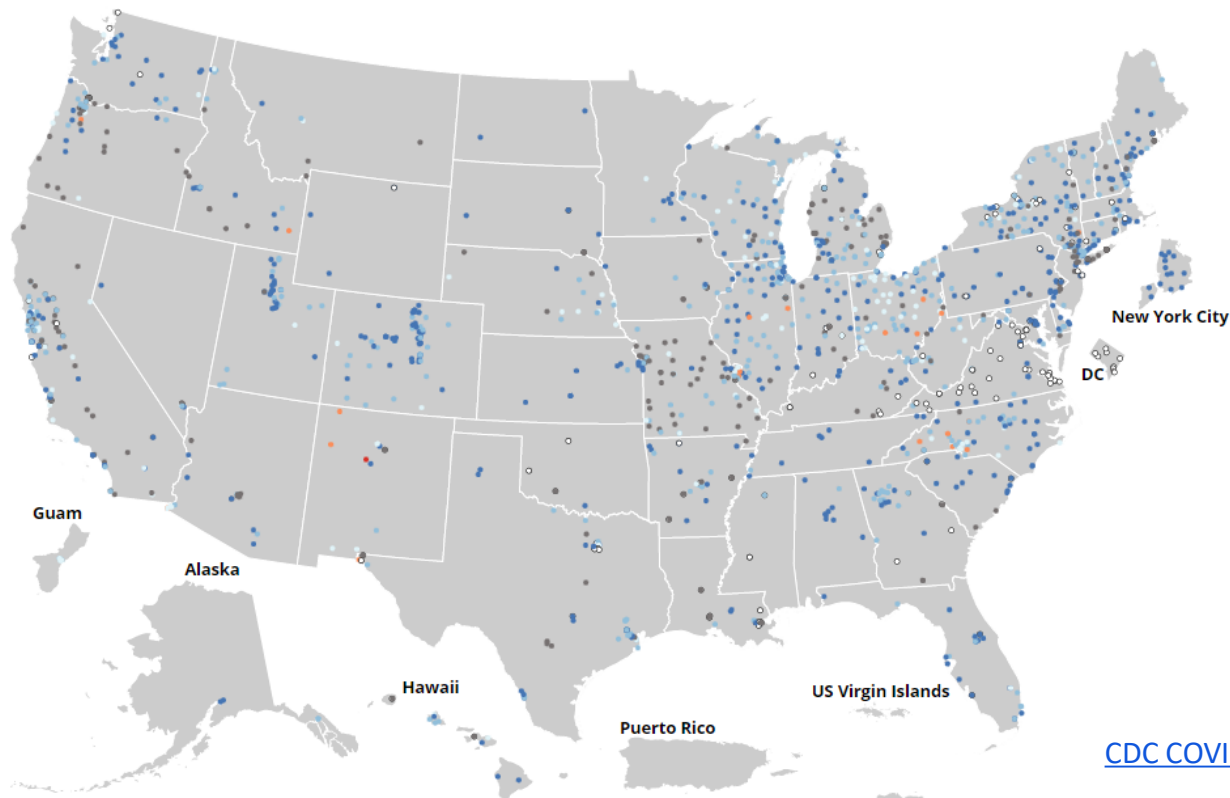
[CDC COVID Data Tracker: Trends by Geographic Area](#)

Another early indicator: voluntary network of laboratories that submit test data

The National Respiratory and Enteric Virus Surveillance System (NREVSS)



Third early indicator: wastewater, especially for ~40% of population covered



Current SARS-CoV-2 virus levels by site, United States

Current virus levels category	Num. sites	% sites	Category change in last 7 days
New Site	148	12	1%
0% to 19%	529	41	- 2%
20% to 39%	429	34	- 12%
40% to 59%	149	12	- 14%
60% to 79%	20	2	- 33%
80% to 100%	1	0	0%

Total sites with current data: 1276

Total number of wastewater sampling sites: 1552

[How is the current SARS-CoV-2 level compared to past levels calculated?](#)

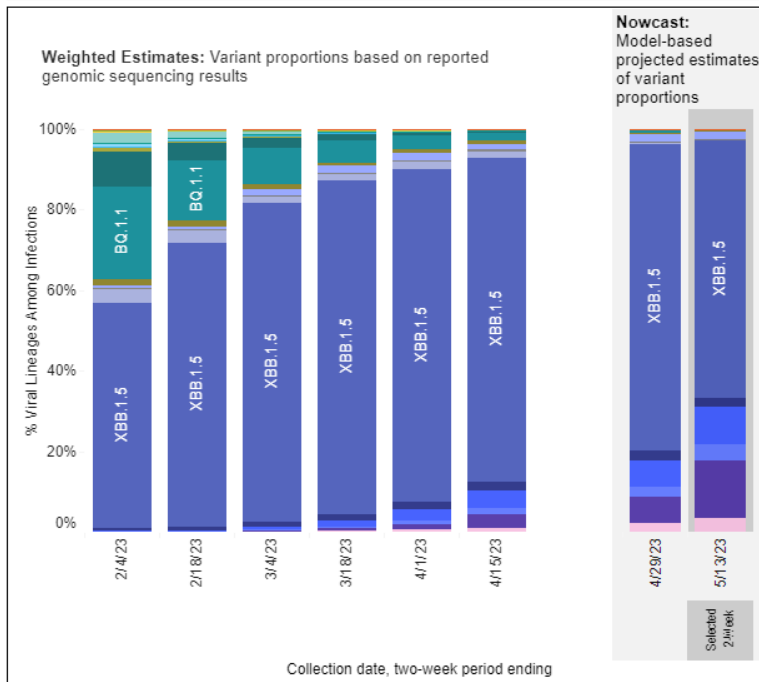
Continue monitoring for new variants

Weighted and Nowcast Estimates in United States for 2-Week Periods in 1/22/2023 – 5/13/2023

Nowcast Estimates in United States for 4/30/2023 – 5/13/2023



Hover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that lineage's estimate.



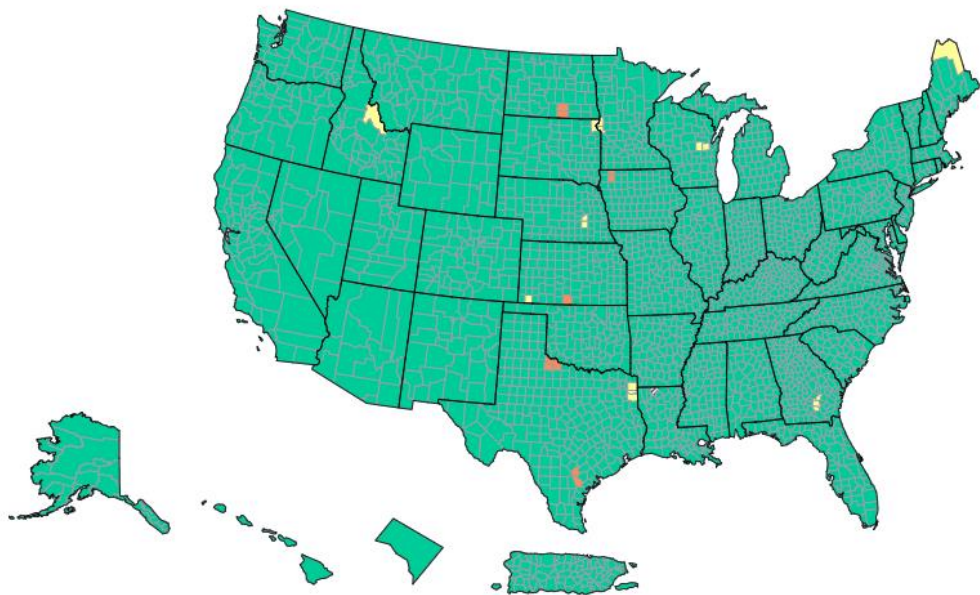
		USA			
WHO label	Lineage #	US Class	%Total	95%PI	
Omicron	XBB.1.5	VOC	64.0%	59.1-68.6%	■
	XBB.1.16	VOC	14.3%	11.1-18.1%	■
	XBB.1.9.1	VOC	9.2%	8.0-10.6%	■
	XBB.1.9.2	VOC	4.0%	3.2-5.1%	■
	XBB.2.3	VOC	3.5%	1.9-6.3%	■
	XBB.1.5.1	VOC	2.4%	1.9-3.0%	■
	FD.2	VOC	1.8%	0.8-4.0%	■
	BQ.1.1	VOC	0.3%	0.1-0.5%	■
	CH.1.1	VOC	0.2%	0.2-0.4%	■
	XBB	VOC	0.2%	0.1-0.4%	■
	BQ.1	VOC	0.0%	0.0-0.1%	■
	BN.1	VOC	0.0%	0.0-0.0%	■
	BA.5	VOC	0.0%	0.0-0.0%	■
	BA.2.12.1	VOC	0.0%	0.0-0.1%	■
	BA.2	VOC	0.0%	0.0-0.0%	■
	BA.2.75	VOC	0.0%	0.0-0.0%	■
BF.7	VOC	0.0%	0.0-0.0%	■	
BA.5.2.6	VOC	0.0%	0.0-0.0%	■	
Other	Other*		0.0%	0.0-0.0%	■

Most significant data changes with end of PHE

- Aggregate case data and national test positivity data ended
- Vaccine administration data use agreements (DUA) ended
 - Mitigated by 60+ individual DUAs
- Impacts on COVID-19 Community Levels and Transmission Levels

COVID-19 hospital admission levels replace COVID-19 Community Levels

US Reported COVID-19 New Hospital Admissions Rate per 100,000 in the Past Week, by County



Counties by hospital admission levels

	Total	Percent
≥ 20.0	10	0.31%
10.0 - 19.9	16	0.5%
<10.0	3195	99.25%

[CDC COVID Data Tracker: Maps by Geographic Area](#)

Know Your COVID-19 Hospital Admission Level

Take action to protect yourself and others in your area from COVID-19.

People may choose to wear a mask at any time. Masks are recommended in indoor public transportation settings and may be required in other places by local or state authorities.



COVID-19 County Check

Find hospital admission levels and prevention steps by county. Data updated weekly.

Select a Location (all fields required)

Georgia



DeKalb County



Go

< Start Over

Low

In **DeKalb County, Georgia**, the COVID-19 hospital admission level is **Low**.

- [Stay up to date](#) with COVID-19 vaccines.
- Maintain [ventilation improvements](#).
- Avoid contact with people who have suspected or confirmed COVID-19.
- Follow recommendations for [isolation](#) if you have suspected or confirmed COVID-19.
- Follow the recommendations for [what to do if you are exposed](#) to someone with COVID-19.
- If you are at [high risk of getting very sick](#), talk with a healthcare provider about additional prevention actions.

People may choose to mask at any time. People with symptoms, a positive test, or exposure to someone with COVID-19 should wear a high-quality [mask or respirator](#) when indoors in public.

If you are immunocompromised, learn more about [how to protect yourself](#).

Find out more about the COVID-19 situation in **DeKalb County, Georgia** with [COVID-19 Data Tracker](#).

[COVID-19 by County | CDC](#)

With end of Transmission Levels, new guidance on masks for healthcare facilities

Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated May 8, 2023 [Print](#)

Implications for the Community Transmission Metric with the End of the Public Health Emergency

With the end of the federal COVID-19 Public Health Emergency (PHE) on May 11, 2023, CDC will no longer receive data needed to publish Community Transmission levels for SARS-CoV-2. This metric informed CDC's recommendations for broader use of source control in healthcare facilities to allow for earlier intervention, to avoid strain on a healthcare system, and to better protect individuals seeking care in these settings.

As described in [CDC's Core IPC Practices](#), source control remains an important intervention during periods of higher respiratory virus transmission. Without the Community Transmission metric, healthcare facilities should identify local metrics that could reflect increasing community respiratory viral activity to determine when broader use of source control in the facility might be warranted (See Appendix).

Corrections and Detention Guidance Updates

Guidance on Management of COVID-19 in Homeless Service Sites and in Correctional and Detention Facilities

Updated May 11, 2023

[Español](#)

[Print](#)

[Guidance on Management of COVID-19 in Homeless Service Sites and in Correctional and Detention Facilities | CDC](#)

Travel guidance updates



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Travelers' Health

Travelers Health > COVID-19

Testing guidance updates

COVID-19 Testing: What You Need to Know

Updated May 11, 2023 [Español](#) [Print](#)

When you get tested:

- Make sure to test at the right time
- Choose the right type of test for your circumstance
- Follow test directions as recommended by FDA

If you do not, your results may be less likely to correctly indicate whether you have COVID-19 or not.

New CDC ventilation target: 5 air changes per hour

Improving Ventilation In Buildings

Updated May 11, 2023

[Español](#)

[Print](#)

What You Need to Know

- To improve ventilation in your building, keep your system operating as designed. Aim for at least 5 air changes each hour and upgrade to MERV-13 filters.
- Good ventilation is essential to maintaining a healthy indoor environment and protecting building occupants from respiratory infections.

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.





COVID-19 Update

June 6, 2023

Michael Stevens, MD, MPH, FSHEA, FIDSA, FACP
System Healthcare Epidemiologist

COVID-19 Update

- Data reporting changes following the end of the public health emergency (PHE)
- How data will be used to inform infection prevention strategies moving forward

“Community Level” vs “Community Transmission”

Community Level

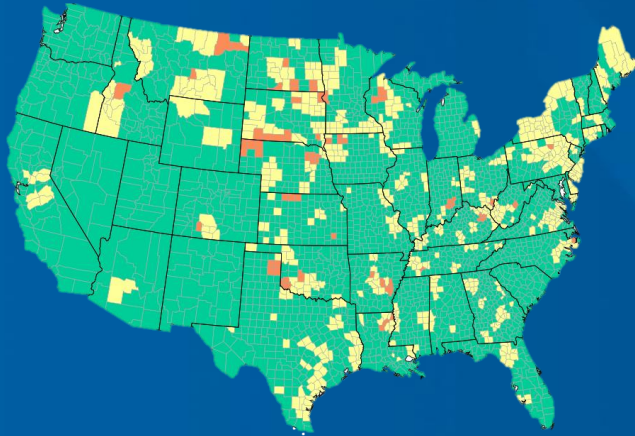
- For community settings
 - 1) New cases
 - 2) COVID-19 admissions
 - 3) % of staffed inpatient beds with COVID-19 patients

Community Transmission

- For healthcare settings
 - 1) New cases
 - 2) % PCR positivity

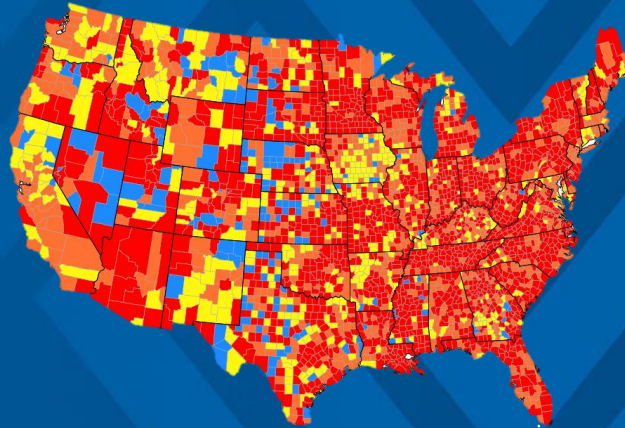
“Community Level” vs “Community Transmission”

Community Level



	Total	Percent	% Change
High	67	2.08%	- 0.46%
Medium	655	20.34%	0.13%
Low	2499	77.58%	0.33%

Community Transmission



	Total	Percent	% Change
High	2416	74.98%	- 1.83%
Substantial	468	14.53%	- 0.12%
Moderate	218	6.77%	0.62%
Low	120	3.72%	1.33%

Data Updates with the End of the Public Health Emergency (PHE)

(Still) Available

- COVID-19 hospital admissions
- COVID-19 deaths
- Emergency Department patient visits with COVID-19
- COVID-19 test positivity
- Wastewater surveillance
- Genomic surveillance
- Count of COVID-19 vaccines administered

Retired

- COVID-19 case and death data (county/state data)
- County-level test positivity data
- V-safe tracking system

Although COVID-19 cases and associated hospitalizations have decreased in recent months, COVID-19 remains an ongoing public health challenge

Updated public health tracking* will keep you informed about COVID-19

Hospital admissions		→ track →	Spread in communities + severity of illness
Death certificates		→ track →	Severity of illness
Emergency department visits		→ track →	Early signs of spread
Genomic sequencing		→ tracks →	New variants



Check [COVID.cdc.gov](https://www.cdc.gov) to know when to take action

*To account for changes in available data after the end of the U.S. Public Health Emergency declaration

bit.ly/mm7219e1

MAY 5, 2023

MMWR

SARS-CoV-2 Data That Are Still Available Following the End of the PHE

Data	Comments
COVID-19 hospital admissions	<ul style="list-style-type: none">• Hospitals required to report through April 2024• Data shifted from daily to weekly reporting• Allows for county-level tracking of severe COVID-19
COVID-19 deaths	<ul style="list-style-type: none">• Source of data has changed; now from the National Vital Statistics System (NVSS)
Emergency Department patient visits with diagnosed COVID-19	<ul style="list-style-type: none">• Data from the National Syndromic Surveillance Program (NSSP); Includes about three-quarters of US ERs
COVID-19 (NAAT) test positivity	<ul style="list-style-type: none">• Source of data has changed; after May 25 = from the National Respiratory and Enteric Virus Surveillance System (NREVSS); over 450 labs that voluntarily submit data
Wastewater surveillance	
Genomic surveillance	<ul style="list-style-type: none">• Reporting biweekly
Count of COVID-19 vaccines administered	<ul style="list-style-type: none">• Continues “for jurisdictions who continue to submit data”• Data now being updated monthly (not weekly)

COVID Data Tracker

Maps, charts, and data provided by CDC, updates Thu by 8pm ET

[COVID-19 Home >](#)

Weekly Update for the United States

Hospitalizations

Hospital Admissions (In Past Week)

8,256

Trend in Hospital Admissions

-11% in past week



Apr 26, 2023 May 23, 2023

Deaths

% Due to COVID-19 (In Past Week)

1.3%

Trend in % COVID-19 Deaths

-13.3% in past week



Apr 1, 2023 May 20, 2023

Vaccinations

% With Updated Booster Dose

17.0%

Total Population



Total Hospitalizations

6,161,377

Total Deaths

1,129,838

Total Updated Booster Doses

56,478,510

CDC | Hospitalization data through: May 20, 2023; Death data through: May 20, 2023; Vaccination data through: May 10, 2023. Posted: May 25, 2023 6:38 PM ET



View Trends >
in Hospitalizations, Deaths, Emergency
Visits, and Test Positivity.



View Maps >
of Hospitalizations, Deaths, Emergency
Visits, and Test Positivity.

Trends in United States COVID-19 Hospitalizations, Deaths, Emergency Visits, and Test Positivity by Geographic Area

Maps, charts, and data provided by CDC, updates weekly on Thu by 8 pm ET[†]

[View Footnotes and Download Data](#)

Select a geographic area: **View (left axis):**

West Virginia

Weekly COVID-19 New Hospital Admissions

View (right axis): —

select one

Weekly COVID-19 New Hospital Admissions per 100,000

Weekly % Deaths Due to COVID-19

Weekly Death Rate Per 100,000 (crude)

Weekly Death Rate Per 100,000 (age-adjusted)

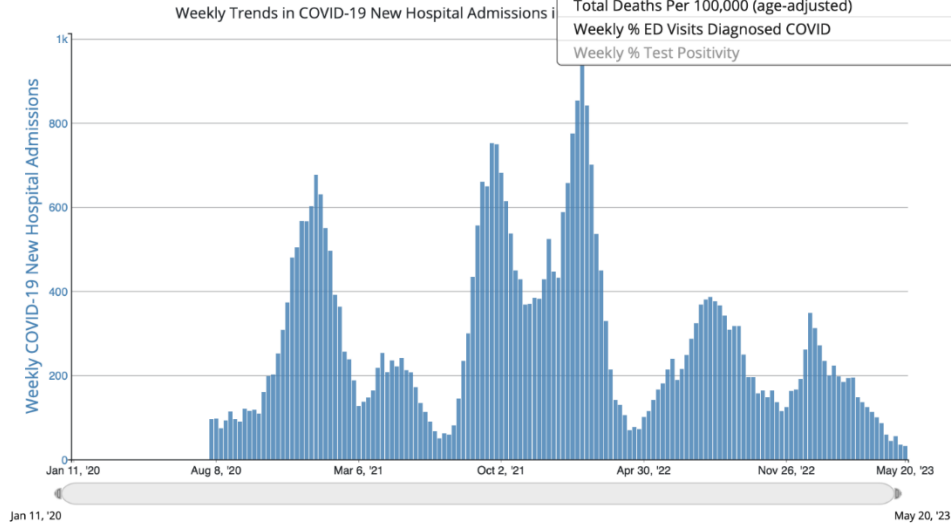
Total Deaths Per 100,000 (crude)

Total Deaths Per 100,000 (age-adjusted)

Weekly % ED Visits Diagnosed COVID

Weekly % Test Positivity

The blue bars show weekly COVID-19 hospital admissions.



SARS-CoV-2 Data That Are Still Available Following the End of the PHE

- County-level
 - Hospitalization data: admissions and inpatient and ICU bed occupancy
- State-level
 - COVID-19-associated deaths
 - ED visits for COVID-19
- HHS region-level
 - % of positive SARS-CoV-2 tests
 - Variant proportions

Impact of Data Reporting Changes

- Movement to weekly reporting will create reporting lag
- Comparing “apples to oranges”
- Data submitted to NHSN on COVID-19 hospital admissions per 100,000 population is the primary surveillance indicator to help guide prevention behaviors
 - Community AND healthcare facilities

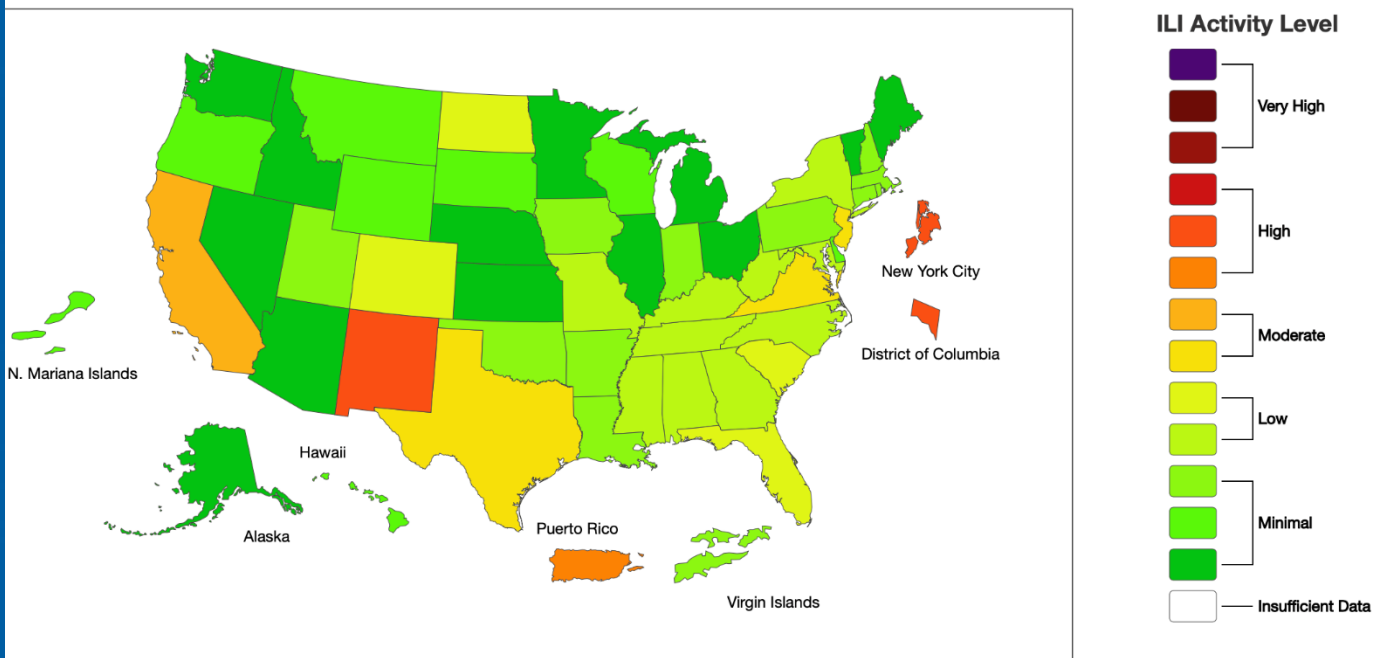
Outstanding Questions

- What data will communities use to inform mitigation efforts (masking, et cetera?)
 - How and when to use these data?
- What data will healthcare facilities use to inform mitigation efforts?
 - Local (facility-specific) data versus (or +) county, state, regional and national data?
 - How and when to use these data?
- Seasonal masking in healthcare facilities

Seasonal Masking Model: 10/1 to 3/31

Model	Healthcare Providers Mask?	Patients Mask?	Visitors Mask?
<i>Respiratory Viral Seasonal Masking” Approach</i> <i>October-March</i>	<ul style="list-style-type: none">• Use state-specific CDC ILI level for October 1-March 31• Universal masking (HCP + Patients + Visitors) when ILI level goes above “low” for any state in the system• Assess ILI levels weekly and consider de-escalating IF ILI rate consistently in “low” category or lower for x2 consecutive weeks		

2022-23 Influenza Season Week 7 ending Feb 18, 2023

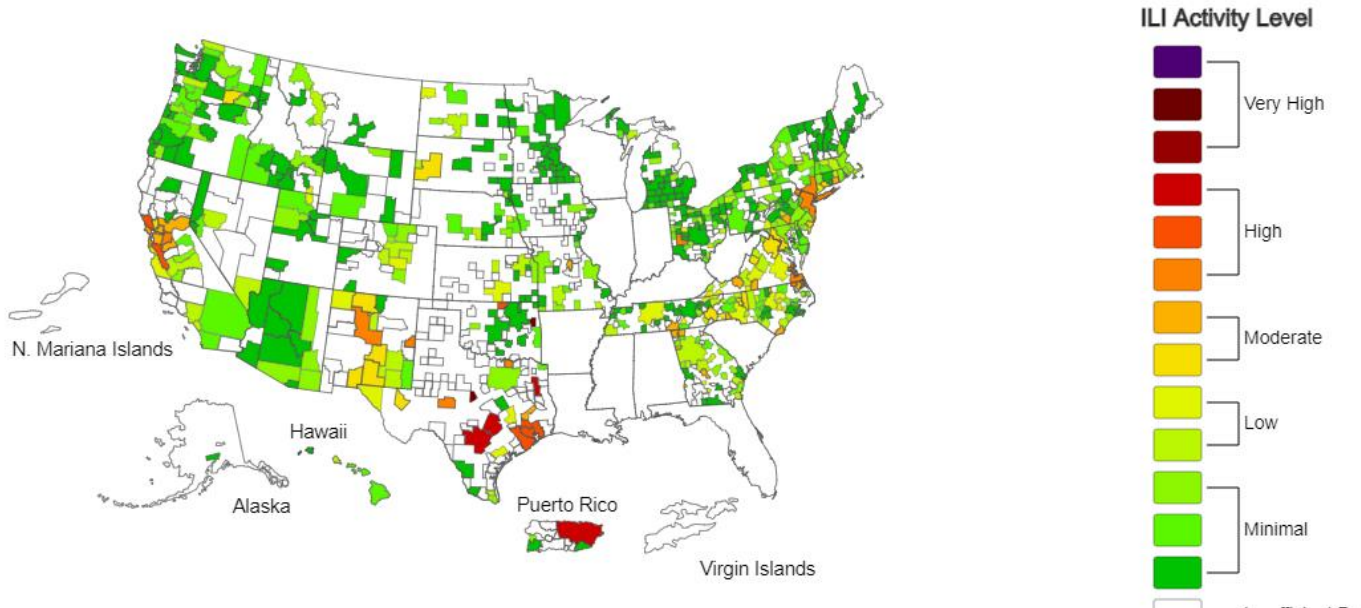


A Weekly Influenza Surveillance Report Prepared by the Influenza Division

Outpatient Respiratory Illness Activity Map Determined by Data Reported to ILINet

This system monitors visits for respiratory illness that includes fever plus a cough or sore throat, also referred to as ILI, not laboratory confirmed influenza and may capture patient visits due to other respiratory pathogens that cause similar symptoms.

2022-23 Influenza Season Week 4 ending Jan 28, 2023



Summary

- Major changes in data reporting have occurred with the end of the public health emergency
- Hospital admissions data represent the most comprehensive and consistent data available
 - The CDC recommends these data inform community and healthcare facility mitigation efforts
- How communities and healthcare facilities use data to inform mitigation strategies for COVID-19 is unclear at this time

Contact Information

- mike.stevens@wvumedicine.org

Availability and Commercialization of COVID Vaccines and Treatment

Meghan E. Pennini, PhD
HHS Coordination Operations and Response Element
(H-CORE)



COVID-19 Therapeutics & Vaccine Distribution Updates

Meghan Pennini, Ph.D.

Chief Vaccine and Therapeutics Officer

HHS Coordination Operations and Response Element (H-CORE)

June 6, 2023

Unclassified/For Public Distribution

Public Health Emergency Declaration Expiration

[White House Fact Sheet: Actions Taken by the Biden-Harris Administration to Ensure Continued COVID-19 Protections and Surge Preparedness After Public Health Emergency Transition](#)

- **Access to COVID-19 vaccines provided by the federal government are not affected** in the months to come. After transition to the traditional health care market, the HHS [Bridge Access Program for COVID-19](#) will provide access to COVID-19 vaccines and treatments for uninsured Americans
- USG will **continue to provide COVID-19 test access for the uninsured** through the [Increasing Community Access To Testing Program](#) (ICATT)
- Protections that provide patients with greater access to health care remain in place (**PREP Act Amendment**)
- **Many major [telehealth flexibilities](#) will remain in place** particularly for those who struggle to find access to care
- Continue to provide accessible information on local COVID-19 risks and **continue to track emerging variants**
- Project NextGen will accelerate and streamline rapid **development of the next generation of COVID-19 vaccines and treatments** through public-private collaborations.
- Continue to invest in efforts to better understand and **address Long COVID**
- **Investments on improving indoor air quality** will drive innovation in ventilation and filtration, building better protection against respiratory illnesses.

HHS Fact Sheet

HHS Fact Sheet: End of the COVID-19 Public Health Emergency

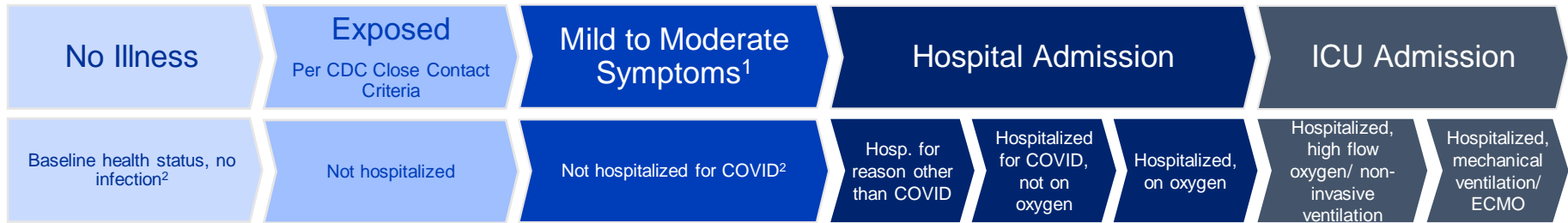
- Since January 2021, **COVID-19 deaths have declined by 95%, hospitalizations down nearly 91%.**
- However, **many people continue to be affected by COVID-19**, particularly seniors, people who are immunocompromised, and people with disabilities; our response to the spread of **SARS-CoV-2 remains a public health priority**.
- Americans **continue to be able to access COVID-19 vaccines at no cost**, just as they did during the COVID-19 PHE, due to the requirements of the [CDC COVID-19 Vaccination Program Provider Agreement](#); people also **continue to be able to access no cost COVID-19 treatments** just as they have during the COVID-19 PHE.
- We will continue to work to protect Americans from the virus and its worst impacts by **supporting access** to COVID-19 vaccines, treatments, and tests, **including for people without health insurance**.
- We will **continue to advance research** into new, innovative vaccines and treatments through an **investment of \$5 billion in Project NextGen**, dedicated program to accelerate and streamline rapid development of next generation vaccines and treatments
- We are continuing to invest in efforts to better understand and address **Long COVID and to help mitigate the impacts**.
- **Once the federal government is no longer purchasing or distributing COVID-19 vaccines and treatments, payment, coverage, and access may change**

HHS Fact Sheet (cont.)

Affected by the end of the COVID-19 PHE:

- Certain Medicare and Medicaid waivers and broad flexibilities for health care providers are no longer necessary and ended
 - To learn more, visit [CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency - PDF](#)
- **Coverage for COVID-19 testing changed**, but USG is maintaining a strong stockpile and distribution channels so that tests remain accessible at no cost in certain community locations; the USG distributed tests through COVIDtests.gov through the end of May.
- **Certain COVID-19 data reporting and surveillance** (e.g., case counts) changed [no change to reporting inventory/use of USG procured products]
- FDA's ability to detect shortages of critical devices related to COVID-19 will be more limited.
- Public Readiness and Emergency Preparedness (**PREP**) **Act liability protections were amended**

Summary of COVID-19 Preventative Agents & Treatments



***COVID19 Vaccines**

None currently authorized for use in any U.S. state or territory.

None currently authorized for use in any US state or territory.

***Oral Antivirals**

- Paxlovid (nirmatrelvir + ritonavir, Pfizer)

***Oral Antivirals**

- Lagevrio (molnupiravir, Merck) – **Alternative**

****IV Antiviral**

- Veklury® (remdesivir, Gilead)

Please see [NIH Current Inpatient Therapies#](https://www.covid19treatmentguidelines.nih.gov/therapies/) (https://www.covid19treatmentguidelines.nih.gov/therapies/)

There is **ample supply** of COVID-19 therapeutics and vaccines

COVID-19 vaccines and oral antiviral treatments remain free beyond the end of the PHE, for as long as USG distributes its supply

*HHS distribution; **USG distribution is continuing beyond PHE**

**Commercially available

¹ [Convalescent Plasma EUA](https://www.fda.gov/media/141478/download) https://www.fda.gov/media/141478/download
High titer convalescent plasma is authorized for specific immunocompromised patients.

² Refer to individual product Fact Sheets for authorization details

#Be sure to check latest updates on inpatient care
[Therapeutic Management of Nonhospitalized Adults With COVID-19](#)
[Therapeutic Management of Hospitalized Adults With COVID-19](#)

Estimated Prevalence of COVID-19 Variants Nationally

Estimates now for 2-week period and updated every 2 weeks

- XBB.1.5 remains most prevalent variant, ~54% estimated prevalence
- Several XBB sub-variants are being tracked separately, including XBB.1.16, XBB.1.9.1, XBB.2.3, XBB1.5.1, FD.2

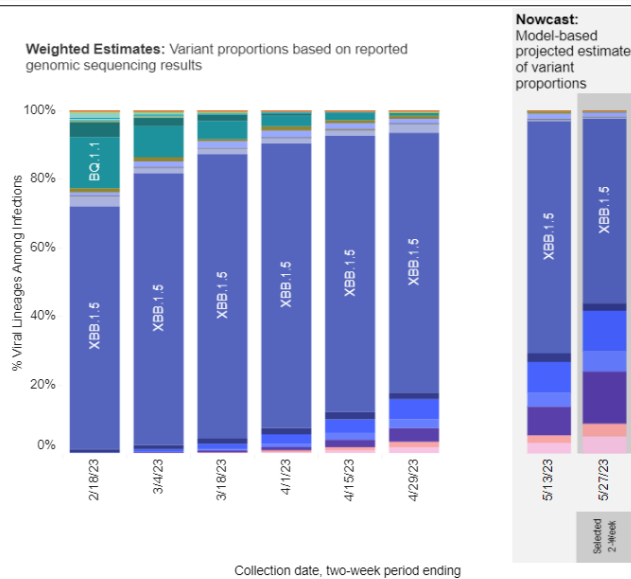
No changes expected to therapeutics portfolio, continue to acquire data

- Paxlovid (nirmatrelvir co-packaged with ritonavir), Veklury (remdesivir), and Lagevrio (molnupiravir) are expected to **retain activity against all circulating variants** based on current data

<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

Weighted and Nowcast Estimates in United States for 2-Week Periods in 2/5/2023 – 5/27/2023

Hover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that lineage's estimate.



Nowcast Estimates in United States for 5/14/2023 – 5/27/2023

USA					
WHO label	Lineage #	US Class	%Total	95%PI	
Omicron	XBB.1.5	VOC	53.8%	50.2-57.4%	
	XBB.1.16	VOC	15.1%	12.1-18.7%	
	XBB.1.9.1	VOC	11.8%	10.3-13.5%	
	XBB.1.9.2	VOC	6.1%	4.7-7.9%	
	XBB.2.3	VOC	4.9%	3.3-7.1%	
	XBB.1.16.1	VOC	3.8%	2.8-5.3%	
	XBB.1.5.1	VOC	2.2%	1.7-2.8%	
	FD.2	VOC	1.5%	0.6-3.5%	
	XBB	VOC	0.4%	0.3-0.7%	
	CH.1.1	VOC	0.2%	0.1-0.3%	
	BQ.1.1	VOC	0.1%	0.1-0.2%	
	BQ.1	VOC	0.0%	0.0-0.1%	
	BA.2	VOC	0.0%	0.0-0.0%	
	BA.5	VOC	0.0%	0.0-0.0%	
	BN.1	VOC	0.0%	0.0-0.0%	
	BA.5.2.6	VOC	0.0%	0.0-0.0%	
Other	Other*		0.0%	0.0-0.0%	

Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. *Other* represents the aggregation of lineages which are circulating <1% nationally during all 2-week periods displayed.
 # BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. Except BA.2.12.1, BA.2.75, XBB and their sublineages, BA.2 sublineages are aggregated with BA.2. Except BA.2.75.2, CH.1.1 and BN.1, BA.2.75 sublineages are aggregated with BA.2.75. Except BA.4.6, sublineages of BA.4 are aggregated to BA.4. Except BF.7, BF.11, BA.5.2.6, BQ.1 and BQ.1.1, sublineages of BA.5 are aggregated to BA.5. Except the lineages shown and their sublineages, sublineages of XBB are aggregated to XBB. Except XBB.1.5.1 and FD.2, sublineages of XBB.1.5 are aggregated to XBB.1.5. Except XBB.1.16.1, sublineages of XBB.1.16 are aggregated to XBB.1.16. For all the other lineages listed, their sublineages are aggregated to the listed parental lineages respectively. Previously, XBB.1.16.1 was aggregated to XBB.1.16. Lineages BA.2.75.2, XBB, XBB.1.5, XBB.1.5.1, FD.2, XBB.1.9.1, XBB.1.9.2, XBB.1.16, XBB.1.16.1, XBB.2.3, BN.1, BA.4.6, BF.7, BF.11, BA.5.2.6 and BQ.1.1 contain the spike substitution R346T.

Paxlovid (nirmatrelvir co-packaged with ritonavir) FDA APPROVAL

- On May 25, 2023, FDA approved a New Drug Application (NDA) for Paxlovid for the treatment of mild to moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death
- The Emergency Use Authorization (EUA) continues to authorize Paxlovid to treat certain eligible pediatric patients, a patient population that is not covered under the approved NDA for Paxlovid at this time
- Paxlovid also remains authorized under EUA to ensure continued access for all eligible patients to the current supply of Paxlovid, including adult patients
- **The product packaged under EUA** – which contains the same tablets (nirmatrelvir tablets and ritonavir tablets) as the Paxlovid that is now FDA-approved – **continues to be available from the federal government at no cost**

COVID-19 Public Health Emergency Declaration Updates/Resources

Additional COVID-19 Public Health Emergency Declaration Updates/Resources

- [May 9, 2023 – FACT SHEET: Actions Taken by the Biden-Harris Administration to Ensure Continued COVID-19 Protections and Surge Preparedness After Public Health Emergency Transition | The White House](#)
- [May 9, 2023 – HHS Fact Sheet: End of the COVID-19 Public Health Emergency](#)
- [May 9, 2023 – Public Readiness and Emergency Preparedness \(PREP\) Act Update](#)
- [May 5, 2023 – FAQs CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency](#)
- [April 18, 2023 – HHS Fact Sheet: HHS Announces ‘HHS Bridge Access Program For COVID-19 Vaccines and Treatments’ to Maintain Access to COVID-19 Care for the Uninsured](#)
- [FAQs: What Happens to EUAs When a Public Health Emergency Ends \(FDA\)](#)
- [ASPR FAQ \(ASPR\)](#)
- [PREP Act Questions and Answers \(ASPR\)](#)
- [PREP Act Coverage and Mpox: Frequently Asked Questions \(ASPR\)](#)
- [Medical Countermeasure Commercialization \(ASPR TRACIE\)](#)

Moving from Emergency Use Authorization to Approval of COVID-19 Treatments: Paxlovid Update

**John Farley, MD, MPH
U.S. Food & Drug Administration**

FDA Update – Approval of Paxlovid

John Farley, MD MPH

Director, Office of Infectious Diseases

Office of New Drugs, Center for Drug Evaluation and Research

June 6, 2023

Paxlovid Approved, EUA Continues (1)



- On May 25, FDA approved Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.
- The EUA continues to authorize Paxlovid for emergency use to treat certain eligible pediatric patients, a patient population that is not covered under the approved NDA for Paxlovid at this time.

Paxlovid Approved, EUA Continues (2)



- Paxlovid also remains authorized under EUA to ensure continued access for all eligible patients to the U.S. government's supply of EUA packaged Paxlovid, including adult patients who are the subject of the approved NDA, pending commercial launch of the approved product.
- The EUA is the current mechanism for Paxlovid access. The use of Paxlovid under the EUA must be consistent with the terms and conditions of the authorization.

[FDA FAQs on the Emergency Use Authorization for Paxlovid](#)

Patients With Prior/Acquired Immunity

- Among patients in EPIC-HR who were antibody positive at trial enrollment, the risk of COVID-19-related hospitalization or death from any cause during 28 days of follow-up was 0.2% among those treated with Paxlovid compared with 1.7% of those receiving placebo.
- EPIC-SR enrolled vaccinated patients with at least one risk factor for progression to severe COVID-19 (and unvaccinated without a risk factor). Among these vaccinated patients, there was a reduction in the risk of COVID-19 related hospitalization or death from any cause with use of PAXLOVID versus placebo, although not statistically significant.

COVID-19 Rebound



- EPIC-HR and EPIC-SR were both randomized placebo-controlled trials, and these trials provide useful data to assess COVID-19 rebound.
- Data from these two trials showed that rebound in SARS-CoV-2 (RNA or virus) shedding or self-reported COVID-19 symptoms occurred in a subset of patients and happened at similar rates in both the patients receiving Paxlovid and placebo.
- Based on the data currently available to FDA, there is not a clear association between Paxlovid treatment and COVID-19 rebound.

Drug-Drug Interactions

- Prior to prescribing Paxlovid, health care providers must: 1) review all medications taken by the patient to assess potential drug-drug interactions with a strong CYP3A inhibitor like Paxlovid and 2) determine if medications require a dose adjustment, interruption, and/or additional monitoring if taken at the same time as Paxlovid.
- Resources for health care providers: [Prescribing Information](#), [EUA Fact Sheet](#), [Prescriber Screening Checklist](#), [NIH COVID-19 Treatment Guidelines](#), [IDSA COVID-19 Treatment Guidelines](#), [Liverpool COVID-19 Drug Interactions Checker](#)

Coverage, Costs & Payment Updates

Will Harris, JD
Centers for Medicare & Medicaid Services

Q&A/ Discussion

Selected Resources

Program Links:

- This webinar is being recorded and can be found with the slides online at <https://www.idsociety.org/cliniciancalls>
- COVID-19 Real-Time Learning Network: <https://www.idsociety.org/covid-19-real-time-learning-network/>
- Vaccine FAQ: <https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/>

Dr. Jackson

- <https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html>
- https://covid.cdc.gov/COVID-data-tracker/#trends_weeklyhospitaladmissions_select_00
- <https://www.cdc.gov/surveillance/nrevss/index.html>
- <https://covid.cdc.gov/COVID-data-tracker/#wastewater-surveillance>
- <https://covid.cdc.gov/COVID-data-tracker/#variant-proportions>
- https://covid.cdc.gov/COVID-data-tracker/#cases_new-admissions-rate-county
- <https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html>
- <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>
- <https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-correctional-settings.html>
- <https://wwwnc.cdc.gov/travel/diseases/covid19>
- <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>
- <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/improving-ventilation-in-buildings.html>

Dr. Stevens

- <https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html>
- <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>
- <https://gis.cdc.gov/grasp/fluview/main.html>

Selected Resources - Cont.

Dr. Pennini

- <https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/09/fact-sheet-actions-taken-by-the-biden-harris-administration-to-ensure-continued-covid-19-protections-and-surge-preparedness-after-public-health-emergency-transition/>
- <https://www.hhs.gov/about/news/2023/04/18/fact-sheet-hhs-announces-hhs-bridge-access-program-covid-19-vaccines-treatments-maintain-access-covid-19-care-uninsured.html>
- <https://www.cdc.gov/icatt/index.html>
- <https://www.cms.gov/files/document/what-do-i-need-know-cms-waivers-flexibilities-and-transition-forward-covid-19-public-health.pdf>
- <https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html>
- <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>
- https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf?utm_source=TWITTER&utm_medium=social&utm_content=20230426_9718651959&utm_campaign=COVID-19&linkId=211653390
- <https://www.covid19treatmentguidelines.nih.gov/therapies/>
- <https://www.covid19treatmentguidelines.nih.gov/management/clinical-management-of-adults/hospitalized-adults--therapeutic-management/>
- <https://www.covid19treatmentguidelines.nih.gov/management/clinical-management-of-adults/nonhospitalized-adults--therapeutic-management/>
- <https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/09/fact-sheet-actions-taken-by-the-biden-harris-administration-to-ensure-continued-covid-19-protections-and-surge-preparedness-after-public-health-emergency-transition/>
- <https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html>
- <https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx>
- https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf?utm_source=TWITTER&utm_medium=social&utm_content=20230426_9718651959&utm_campaign=COVID-19&linkId=211653390

Selected Resources – Cont.

Dr. Pennini – cont.

- <https://www.hhs.gov/about/news/2023/04/18/fact-sheet-hhs-announces-hhs-bridge-access-program-covid-19-vaccines-treatments-maintain-access-covid-19-care-uninsured.html>
- https://aspr.hhs.gov/COVID-19/Pages/COVID_FAQs.aspx
- <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends>
- <https://aspr.hhs.gov/legal/PREPact/Pages/PREP-Act-Question-and-Answers.aspx#COVID>
- <https://asprtracie.hhs.gov/technical-resources/159/medical-countermeasure-commercialization/0>

Dr. Farley

- <https://www.fda.gov/media/155052/download>
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217188s000lbl.pdf
- <https://www.fda.gov/media/155050/download>
- <https://www.fda.gov/media/158165/download>
- <https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/>
- <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>
- <https://www.covid19-druginteractions.org/>

Mr. Harris

- <https://www.cms.gov/files/document/transcriptofficehoursendingphe04252023.pdf>
- <https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf>

THANK YOU

We want to hear from you!

Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at

www.idsociety.org/cliniciancalls

-- library of all past calls available --

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